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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,284	02/09/2004	Yuan Y. Lee	USP2270A-YYL	1138

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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,284	LEE, YUAN Y.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-43* is/are pending in the application.

4a) Of the above claim(s) *3,5 and 40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 5-43 are pending in the application.

Claims 5-35 were withdrawn from the merits in the previous Office Action as they are directed toward a non-elected invention elected without traverse in the response submitted on 5/17/06.

Newly submitted claims 40-43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 40-43 ('Group V') are drawn to a method for making the composition of claim 40. Inventions I (corresponding to claims 36-39) and Group V (corresponding to claims 40-43) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the Invention of Group I can be made by a materially different process. For example, the herbal materials of Group I can simply be mixed together to form the composition, and therefore, do not require the particulars of Group V.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-43 are hereby withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be

maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 36-39 were examined on their merits.

Applicant's arguments pertaining to 40-43 are rendered moot because these claims are not under examination at this time.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 103

Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (US 5,741,491) in view of Yang et al. (2003).

Claims are essentially directed toward the same subject matter as previous claims 1-4; however, Applicant is now claiming wherein the composition has antiinflammatory properties and further 'wherein said composition is interactively providing an elevated effect of treatment of diabetes, arthritis and neuralgia'. This new intended use will be discussed *infra.*

Applicant's arguments were fully considered, but were not found persuasive.

Applicant initially reiterates the statute under this code, and argues that "the differences between the subject matter sought to be patented as a whole of the instant invention and Jones which is qualified as prior art of the instant invention under 35 USC 102 are obvious in view of Yang at the time the invention was made to a person having ordinary skill in the art....". It is noted that this rejection is made under 35 USC 103(a) and not 35 USC 102 as Applicant contends.

Applicant argues that Jones does not teach the incorporation of *Toona sinensis* and Heracleum: "Jones is silent regarding how to combine Heracleum lanatum with Toona sinensis to form the herbal composition". In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking

references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the Instant case, it is true that Jones does not teach the incorporation of Heracleum lanatum, hence the reason for the rejection under 35 USC 103(a) and not 35 USC 102.

Applicant argues that "The Applicant respectfully submits that the composition of Heracleum lanatum and a species of Populus taught by Jones can only [be] used for treatment of diabetes. The composition of Toona sinensis and Heracleum lanatum as disclosed by the instant invention is used for treatment of diabetes mellitus, arthritis, and neuralgia" (p. 9, Remarks)In response to applicant's argument that the combination of herbs can be used for treating arthritis and neuralgia, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The Examiner has considered the claim language as well as the Specification for objective evidence in the form of unexpected results. It is first noted that the new language in the claims which states that the composition is used for treatment of arthritis and neuralgia is the intended use of the composition and does not materially change the composition. Further, it is noted that these ailments would not be unexpected considering that Toona sinensis was *already known in the art for possessing strong anti-inflammatory and analgesic properties* (pp. 5-6, Instant

specification). Further, as more keenly pointed out *infra*, the ordinary artisan would have been motivated to combine the herbs even if Applicant combined the herbs for a different reason (that is, for treating more ailments than just diabetes).

Applicant argues that "the chemical reaction between Heracleum lanatum and a species of Populus taught by Jones is totally different from the chemical reaction between Toona sinensis and Heracleum lanatum as disclosed in the instant invention. In fact, the composition of Toona sinensis and Heracleum lanatum can compensate, complement and maximized [*sic*, maximize] the treatment for diabetes mellitus, arthritis and neuralgia" (p. 9, Remarks). However, Applicant's arguments are speculative, as there is no evidence found in the Specification of 'maximized' results with regard to diabetes, arthritis and neuralgia treatment with the combination of *T.sinensis* and *H. lanatum*. What would be expected from one of ordinary skill in the art, in light of the combination of references, is that because each individual herb is known in the art for treating diabetes, that the combination of herbs would provide for an additive effect: "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

Applicant argues: "Jones fails to teach 'Toona sinensis is leaves of Toona sinensis and heracleum is roots of heracleum'...Jones is silent regarding any use of Toona sinensis" (p. 9, Remarks). Again, Applicant is arguing the references individually, wherein the rejection is based upon the combination of references. The MPEP states:

> The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a **convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination**. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). emphasis added

In the Instant case, the prior art intrinsically provides the advantage for the combination of *H.lanatum* and *T. sinensis* because it is clear that the prior art taught that each herb and parts thereof respectively (Jones teaches the root of Heracleum is useful for treating diabetes and Yang et al. taught that the active ingredient of Toona sinensis was found in the leaves) were known in the art for treating diabetes. Therefore, one of ordinary skill in the art would have had a reasonable expectation that the combination of Heracleum lanatum roots and Toona sinensis leaves would have provided an additive effect on treating diabetes.

Applicant argues that Jones fails to teach that " ' The quantity of Toona sinensis is not less than the quantity of Heracleum lanatum by weight' " (p. 10, Remarks). It is true that Jones does not teach this aspect of the claimed invention, however, Applicant again is arguing the reference alone, wherein the rejection is made upon a combination of Jones in view of Yang et al. Although the prior art did not specifically teach that the quantity of Toona sinensis is 'not less than the quantity of Heracleum lanatum', one of ordinary skill in the art would have been motivated to combine the *T.sinensis* and *H.lanatum* in equal amounts to provide for an additive effect with regard to diabetes treatment. Equal amounts is 'not less than' the quantity of *H. lanatum*. In addition the MPEP further states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Applicant argues that "...when applying 35 USC 103, the following tenants of patent law must be adhered to...(a)...(b)...(c)...(d)....is determined" (p. 10, Remarks). In response, the Examiner indicates that the claimed invention has been considered as a whole, in light of the specification, and in light of the knowledge of the ordinary artisan at the time the invention was made. The prior art suggests the desirability of the claimed invention because it was obvious to combine compounds which were known for the

same purpose in order to form another composition for the same exact purpose. The ordinary artisan would have been motivated to do so to provide an additive effect on treating diabetes. The references were viewed without the benefit of hindsight vision in that each reference, prior to Invention was already known in the art for treating diabetes. The Examiner did not draw on any foresight found in the Instant specification to render this conclusion; as it was already clear from the prior art that each herb was known in the art for treating diabetes. Therefore, again, at the time the invention was made, it would have been desirable to combine *T. sinensis* leaves and *H. lanatum* roots at equal proportions in order to treat diabetes.

Applicant argues "The mere fact that a reference.....*Libbey-Owens-Ford v. BOC Group*... (p. 10, Remarks). Again, the prior art implicitly suggested the combination of references in that each of *T.sinensis* and *H.lanatum* were both known in the art for lowering blood glucose levels; therefore, the ordinary artisan would have *expected* that the combination of *T.sinensis* and *H.lanatum* would provide for an additive result with regard to blood glucose levels. There is no evidence in the Specification which would indicate that the combination of herbs would provide for anything more than an additive effect, which, again, would be expected.

Applicant argues "Yang et al. merely teaches ....without any mention of any suggestion of how such extracted substance be possible incorporating with Heracleum lanatum to form the herbal composition...neither Jones nor Yang et al. suggests a

herbal composition of Toona sinensis and Heracleum containing the above distinctive features 9 (a) to (f) as claimed....for interactively providing an elevated effect of treatment [of] diabetes, arthritis and neuralgia" (pp. 10-11, Remarks). However, again, the suggestion for combining the references need not be explicitly stated in the references. The motivation for combining the references comes from the consideration that 1) both references are analogous art; in that they are both directed toward treating diabetes (lowering blood glucose levels) with medicinal herbals, 2) stemming from the prior art it is clear that there was a desirability in finding herbal treatments for lowering blood glucose levels and 3) it is known that combinations of medicines which are known for the same purpose are expected to provide for additive effects. Further, with regard to treatment of neuralgia and arthritis; first, it is noted that T. sinensis was already known for this purpose, further, the MPEP states that

> The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. >See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem

addressed in a prior art reference to be motivated to apply its teachings.");< *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) (discussed below). Although *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (Bd. Pat. App. & Inter. 1993) states that obviousness cannot be established by combining references "without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done" (emphasis added), reading the quotation in context it is clear that while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention (see MPEP § 2015).

Here, the desirability of combining the herbs was present in the art because each one was known for treating diabetes. The language in the claims which states 'elevated effect of treatment of diabetes, arthritis and neuralgia' is merely intended use language. Although the combination of herbs may provide for an effect of treating arthritis and neuralgia, this is not considered an unexpected result with regard to diabetes treatment; that is, the claims remain obvious in light of the combination of references because the desirability of the combination of *T.sinensis* and *H. lanatum* was already found in the prior art; Again, "It is not necessary that the prior art suggest the combination *to achieve the same advantage or result discovered by applicant*" (see above, *In re Kahn*, emphasis added). "*The recitation of an additional advantage associated with doing*

what the prior art suggests does not lend patentability to an otherwise unpatentable invention." *In re Lintner*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) and In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990) (emphasis added). Further, as stated *supra*, taking the disclosure as a whole into consideration, it does not appear that the combination of *T.sinensis* and *H. lanatum* provide for any unexpected results with regard to any new properties stemming from the mixture of the herbs such as a synergistic effect of treating diabetes. Further, the Specification explicitly teaches that *T.sinensis* was already a known antiinflammatory, analgesic and anti-arthritic medicine. Therefore, in this respect, it is not conclusive that a treatment of neuralgia (facial pain) is an 'advantage' of the combination of the herbal ingredients because *T:sinensis* was already a known analgesic as admitted by Applicant.

Applicant argues that ' "To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. in other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited art...in the manner claimed...[T]he suggestion to combine requirement sands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness' *In re Gorman*... (p. 11, Remarks).

Again, the Instant rejection was not based upon hindsight reasoning, as the Instant specification was not used as a basis for rejection. The claims are obvious over the specific teachings in the respective references. There is a motivation to combine the references in that each was known in the art for treating diabetes. Therefore, the knowledge that each herb was known in the art for treating diabetes was generally available to one of ordinary skill in the art at the time the invention was made.

Applicant argues that "...neither Jones nor Yang et al, separately or in combination, suggests or makes any mention whatsoever of the difference [sic, different] subject features (a) to (f) as claimed in the amended claims 36-43 of the instant invention" (p. 11, Remarks). The Examiner respectfully disagrees and points to the remarks to Applicant's arguments *supra.*

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the references.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

December 19, 2006